

During the interview, Applicants' representatives and the Examiner also discussed the rejection under 35 USC § 103. Applicants reiterated that the values present in the USDA reference do not refer only to the aglycones, but actually refer to a theoretical value which is the combination of the aglycones and a calculated value which corresponds to the glucosides. The Examiner appeared to have difficulty agreeing with this position, since the Table (in the USDA reference) states "Daidzein" next to a numerical value, and "Genistein" next to a numerical value. The Examiner indicated that it may be helpful to submit a Declaration Under Rule 1.132, signed by an inventor, further supporting Applicants' position. In accordance with this suggestion by the Examiner, Applicants submit herewith a Declaration Under 37 CFR 1.132, signed by a co-inventor of the application.

During the interview, Applicants' representatives and the Examiner also discussed the rejection under 35 USC § 112, first paragraph. Applicants directed the Examiner to the disclosure on pages 5 and 6 of the specification to support the argument that the specification does provide written description for the claims. The Examiner recommended that Applicants provide an English translation of the relevant portions of JP 1987-126186, as discussed on page 6 of the specification. Additionally, the Examiner suggested that Applicants also provide comments regarding how the treatment step (acid heating or enzyme hydrolysis) changes the ratio of genistein to daidzein from that which is present prior to treatment to the ratio recited in Applicants' claims. Again, in accordance with the Examiner's suggestion, Applicants provide herewith an English translation of JP 1987-126186, as well as comments regarding how the treatment step changes the relevant ratio.

Applicants kindly thank the Examiner for providing helpful suggestions for expediting prosecution of the above-identified application.

Claim of Priority

As noted above, during the personal interview of October 7, 2009, the Examiner acknowledged that the certified copy of the priority document is present in the Image File Wrapper for this application. Accordingly, Applicants respectfully request that the Examiner acknowledge the claim for foreign priority, as well as receipt of the certified copy of the priority document, with the next correspondence.

Rejection under 35 USC § 112, First Paragraph

Claims 1-5, 12, 13, 17 and 18 are rejected under 35 USC § 112, first paragraph, as failing to comply with the written description requirement.

The Examiner indicates that the claims are drawn to a soy isoflavone aglycone wherein the soy isoflavone aglycone is obtained from or in an extract from whole-grain soy; the genistein/daidzein weight ratio in the soy isoflavone aglycone is in the range of 1/1 to 1.5/1, and the proportion of the total weight of genistein to daidzein in the soy isoflavone aglycone is at least 90%. Accordingly, the Examiner asserts that the claims are drawn to a genus of compounds that is defined only by a nebulous percent and a nebulous ratio.

Applicants direct the Examiner's attention to page 5, line 34 to page 6, line 8 of the specification, which describes that soy isoflavone aglycone is obtained by subjecting the obtained glycoside (from the soybean) to acid heating or β -glucuronidase enzyme hydrolysis in a purification step. This is necessary in order to convert the glycosides into non-glycosides, i.e., genistein and daidzein. Applicants respectfully assert that one of ordinary skill in the art would easily understand the meaning of these well known steps.

Additionally, as requested by the Examiner during the personal interview, Applicants enclose herewith an English translation of JP 1987-126186, as discussed on page 6, line 6 of Applicants' specification.

Furthermore, Applicants direct the Examiner's attention to US 2001/0010930, cited in the Information Disclosure Statement filed concurrently herewith. Applicants respectfully submit that one of ordinary skill in the art would be able to change the ratio of aglycone included in soybeans to the specific ratio recited in Applicants' claims, based on the information available when the present application was filed e.g., US 2001/0010930.

Accordingly, Applicants respectfully assert that the disclosure of the specification, taken together with the knowledge of one of ordinary skill in the art at the time the application was filed, clearly provides written description for the pending claims. Thus, it is respectfully requested that the above-rejection be withdrawn.

Rejection under 35 USC § 103(a)

Claims 1-5, 12, 13, 17 and 18 are rejected under 35 USC § 103(a) as being unpatentable over Lovett (US Patent No. 6,881,419) in view of USDA-Iowa State University Database on the Isoflavone Content of Foods, 1999 (hereafter, “USDA”). In response to this rejection, Applicants direct the Examiner’s attention to the Declaration under 37 CFR 1.132, which is submitted herewith. In view of the explanation provided in the Declaration, it is clear that the values set forth in the USDA reference do not represent only the amount of aglycone forms present in the soy flour. Thus, the combination of Lovett and USDA does not render the subject matter of Applicants’ claims obvious. Accordingly, it is respectfully requested that the above-rejection be withdrawn.

Conclusion

In view of the foregoing remarks, it is submitted that each of the grounds of rejection set forth by the Examiner has been overcome, and that the application is in condition for allowance. Such allowance is solicited.

If, after reviewing this response, the Examiner feels there are any issues remaining which must be resolved before the application can be passed to issue, the Examiner is respectfully requested to contact the undersigned by telephone in order to resolve such issues.

Respectfully submitted,

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